K090857 1/1

JUL 14 2009

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the VALOR™ Ankle Fusion Nail System.

Submitted By:	Wright Medical Technology, Inc.
Date:	June 9, 2009
Contact Person:	Kellen Hills Regulatory Affairs Specialist
Proprietary Name:	**VALOR™ Ankle Fusion Nail System**
Common Name:	Ankle Fusion Nail
Regulation Number and Classification:	21 CFR 888.3020 – Class II
Product Code:	HSB: Rod, Fixation, Intramedullary and Accessories

DEVICE INFORMATION

A. INTENDED USE

The VALOR™ Ankle Fusion Nail System is intended to facilitate tibiotalocalcaneal arthrodesis to treat severe foot/ankle deformity, arthritis, instability, and skeletal defects after tumor resection. These include Neuro-osteoarthropathy (Charcot's Foot), Avascular Necrosis of the talus, failed joint replacement, failed ankle fusion, distal tibia fracture non-unions, Osteoarthritis, Rheumatoid Arthritis, and Pseudoarthrosis.

B. DEVICE DESCRIPTION

The design features of the VALOR™ Ankle Fusion Nail System are described below.

- Nails and screws are manufactured from titanium alloy
- Nails are available in two diameters and a range of lengths
- Screws are available in one diameter and a range of lengths

The design features of the VALOR™ Ankle Fusion Nail System are substantially equivalent to the design features of other devices previously cleared for market.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the VALOR™ Ankle Fusion Nail System are substantially equivalent to previously cleared predicate devices. The safety and effectiveness of the VALOR™ Ankle Fusion Nail System is adequately supported by the substantial equivalence information, materials information and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wright Medical Technology, Inc.
% Mr. Kellen Hills
5677 Airline Road
Arlington, TN 38002

JUL 14 2009

Re: K090857
Trade/Device Name: VALOR Ankle Fusion Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: June 15, 2009
Received: June 18, 2009

Dear Mr. Hills:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's

(CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090857

Device Name: VALOR™ Ankle Fusion Nail System

Indications For Use:

The VALOR™ Ankle Fusion Nail System is intended to facilitate tibiotalocalcaneal arthrodesis to treat severe foot/ankle deformity, arthritis, instability, and skeletal defects after tumor resection. These include Neuro-osteoarthropathy (Charcot's Foot), Avascular Necrosis of the talus, failed joint replacement, failed ankle fusion, distal tibia fracture non-unions, Osteoarthritis, Rheumatoid Arthritis, and Pseudoarthrosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090857